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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,837	04/10/2007	Heike Barlag	32860-001100/US	9815
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EXAMINER DIETTERLE, JENNIFER M				
ART UNIT		PAPER NUMBER		
1759				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/587,837

Applicant(s)

BARLAG ET AL.

Examiner

JENNIFER DIETERLE

Art Unit

1759

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/16/11.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 2, 7-10, 25 and 28 is/are allowed.
- 6) ☒ Claim(s) 3-6, 21-24, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

Claims 1-28 are pending.

Claims 11-20 have been withdrawn **without** traverse in the reply filed on 8/18/10.

Claims 1, 2, 7-10, 25 and 28 are allowed.

Claims 3-6, 21-24, 26 and 27 are rejected below.

Comments

1. The rejection of claim 1 and claims 2-10, 21-25 and 28, which depend from claim 1, under 35 U.S.C. 112, first paragraph has been withdrawn due to applicant's amendments thereof.
2. **The rejection of claim 3 under 35 U.S.C. 112, second paragraph is maintained. Claim 3 recites the limitation "when measuring oxidation currents" in line 2; however, there is no mention of *measuring oxidation currents* in claim 1. Claim 1 recites measuring a single oxidation current. There is insufficient antecedent basis for these limitations in the claim. Since claims 5, 6, 21 and 22 depend from claim 3, they are rejected.**
3. **Claim 4 is rejected under 35 U.S.C. 112, second paragraph is maintained. Claim 4 recites the limitation "measuring reduction currents" in line 2; however, there is no mention of *measuring reduction currents* in claim 1. Claim 1 only**

recites measuring a single reduction current. There is insufficient antecedent basis for these limitations in the claim. Since claims 23 and 24 depend from claim 4, they are rejected.

Response to Arguments

4. Applicant's arguments filed 6/16/11 have been fully considered and are persuasive for the method claims, but they are not persuasive for the device claims.

Applicant remarks concerning the rejection of claims 26 and 27 are not persuasive. Applicant remarks that neither Bindra et al. nor Henkins et al. teach a device for selecting and measuring pulse lengths so that at the end of the pulse, a capacitive current is small in comparison with a Faraday current or for selecting the relaxation phase pulse" lengths so that at the end of the pulse the concentration gradient is relaxed so that at the beginning of a following measuring phase the change in concentration of the mediator is reversible. Applicant is reminded that device claims are examined based on structure and not function. It is noted that claims 26 and 27 contain numerous references of *intended use*. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458,459 (CCPA 1963).

In the present case, the examiner maintains that both Bindra et al. and Henkens et al. are both capable of performing the intended use. First, Bindra et al. teach a biosensor comprising a means, i.e. PARC Model 400, for pulsing the potential of the working electrode between measuring and relaxation phases (see col. 1 on page 2567 under Apparatus and Nafion Coating headings). If the PARC is designed to apply a repeating sequence of three applied potentials (i.e. measure, oxidize, and reactivate) according to a specified timing, this would read on the means for selecting measuring phase pulse length and relaxation pulse length as the device is programmable. Bindra et al. also teach the use of a Princeton Applied Research Model 400 electrochemical detector which can measure the change in concentration of an analyte and a Shimadzu CR 4A integrator which is used to process the detector output. Additionally, Henkens et al. teach pulsed electrochemical detection in which there is a means for applying a series of pulses which itself can be programmed by a user as to what pulse lengths, times, and strengths (i.e. means for selecting and multiplexed potentiostat) and a detection/measuring means (i.e. electrochemical pulse analyzer)(col. 5, lines 1-20; col. 6, lines 15-35). Therefore, both Henkens et al. and Bindra et al. teach devices comprising a means to apply a pulse (i.e. PARC Model 400 or multiplexed potentiostat) and detect/measure a reaction (i.e. Princeton Applied Research Model 400 or electrochemical pulse analyzer) which are capable of performing the intended use stated in claims 26 and 27.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 3 is rejected under 35 U.S.C. 112, second paragraph. Claim 3 recites the limitation "when measuring oxidation currents" in line 2; however, there is no mention of *measuring oxidation currents* in claim 1. Claim 1 only recites the measurement of a single measurement oxidation current. There is insufficient antecedent basis for these limitations in the claim. Since claims 5, 6, 21 and 22 depend from claim 3, they are rejected.
6. Claim 4 is rejected under 35 U.S.C. 112, second paragraph. Claim 4 recites the limitation "measuring reduction currents" in line 2; however, there is no mention of *measuring reduction currents* in claim 1. Claim 1 only recites the measurement of a single reduction current. There is insufficient antecedent basis for these limitations in the claim. Since claims 23 and 24 depend from claim 4 they are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Bindra et al. (Anal. Chem. 1989, 61 2566-2570, see col. 1 on page 256).

Regarding claims 26 and 27, Bindra et al. teach a biosensor comprising a means, i.e. PARC Model 400, for pulsing the potential of the working electrode between measuring and relaxation phases (see col. 1 on page 2567 under Apparatus and Nafion Coating headings). The PARC is designed to apply a repeating sequence of three applied potentials (i.e. measure, oxidize, and reactivate) according to a specified timing, this would read on the means for selecting measuring phase pulse length and relaxation pulse length as the device is programmable. Finally, Bindra et al. teach the use of a Princeton Applied Research Model 400 electrochemical detector and a Shimadzu CR 4A integrator which is used to process the detector output.

It is noted that claims 26 and 27 contain numerous recitations of the intended use of the claimed invention which must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458,459 (CCPA 1963). As noted above, a potentiostat has the capability for applying pulsed potentials of oxidation and reduction currents to a sample. Additionally, since the potentiostat is programmable, it has the capability of being programmed based on measurements obtained through the detector for a particular user's preferences.

8. Claims 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Henkens et al. (US 6,391,558 B1).

Regarding claims 26 and 27, Henkens et al. teach pulsed electrochemical detection in which there is a means for applying a series of pulses which itself can be programmed by a user as to what pulse lengths, times, and strengths (i.e. means for selecting and multiplexed potentiostat) and a detection/measuring means (i.e. electrochemical pulse analyzer)(col. 5, lines 1-20; col. 6, lines 15-35) that has the capability to measure oxidation and reduction currents.

Again, it is noted that claims 26 and 27 contain numerous recitations of the intended use of the claimed invention which must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458,459 (CCPA 1963). As noted above, a potentiostat has the capability for applying pulsed potentials of oxidation and reduction currents to a sample. Additionally, since the potentiostat is programmable, it has the capability of being programmed based on measurements obtained through the detector for a particular user's preferences.

9. Claims 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Gumbrecht et al. WO02/42759 (citing to US 2004/0063152 A1 as translation).

Regarding claims 26 and 27, Gumbrecht et al. teach a redox recycling apparatus that contains at least three electrodes, a potentiostat, and an evaluation circuit which allows for the measurement of the redox potential by means of electrochemical measurement signals (sections 0057-60, additionally see entire document). The device has the capability through its electrodes to supply an oxidation and a reduction (i.e. the definition of redox recycling, section 0002) pulse to the system in order to allow for the oxidation and then the reduction of an analyte such as p-aminophenol to quinoneimine (see section 0033). The system of Gumbrecht et al. forms a complete measuring arrangement for electrochemical analysis which is suitable for redox recycling (section 0062).

It is noted that claims 26 and 27 contain numerous recitations of the intended use of the claimed invention which must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458,459 (CCPA 1963). As noted above, a potentiostat has the capability for applying pulsed potentials of oxidation and reduction currents to a sample. Additionally, since the potentiostat is programmable, it has the capability of being programmed based on measurements obtained through the detector for a particular user's preferences.

Allowable Subject Matter

Claims 1, 2, 7-10, 25 and 28 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: Claim 1 claims a method for measuring at least one of a concentration and change in concentration of a redox-active substance as a mediator in which the method comprises measuring an oxidation current and measuring a reduction current.

The closest prior art of record, Gunasingham et al. teach a method for the detection of glucose using a tetrathiafulvalene (TTF) mediated enzyme electrode and pulsed amperometric detection in which the system is maintained in a reduction potential and is switched to an oxidation potential only for a few hundred ms during each pulse cycle (page 350). Gunasingham et al. teach a method that incorporates the measurement of an oxidation current (see figure 1); However, Gunasingham et al. does not specifically teach a method for measuring a reduction current. Gunasingham et al. applies a pulse duration in which the discharge current decreases and when the sampled current reaches a constant value, only the faradic current is significant. In other words, the amount of oxidized mediator reaches a steady state. The steady state in Gunasingham et al. is the relaxation phase; therefore, Gunasingham et al. does not measure a reduction current to obtain a relaxation phase.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER DIETERLE whose telephone number is (571)270-7872. The examiner can normally be reached on Monday thru Thursday, 9am to 4pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Barton can be reached on (571) 272-1307. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMD
8/3/11

/Jeffrey T Barton/
Supervisory Patent Examiner, Art Unit 1759
5 August 2011